IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patentee:	Snyder	}	
U.S. Patent No.	6,342,482	}	
Issue Date:	January 29, 2002	}	FILED ELECTRONICALLY May 26, 2011
Title:	Formulations For Controlling Human Lice	}	
Assignee:	Eli Lilly and Company	}	
Attorney Docket No.	X12227A_US	}	

COMMUNICATION

Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Transmitted herewith is supplemental communication for the Application for Extension of Patent Term Under 35 U.S.C. § 156 submitted on March 17, 2011 with respect to the above-captioned patent. Pursuant to the Examiner's request, this filing includes pages 12 through 14 of the Application numbered according to the submission on March 17, 2011.

Applicant believes that no fees are required with this filing. However, if any fees are required, the Commissioner is hereby authorized to charge those fees, or credit any overpayment, to Deposit Account No. 05-0840 in the name of Eli Lilly and Company and any additional fees which may be required.

Respectfully submitted,

/James J. Sales/
James J. Sales
Attorney Reg. No. 33,773

(a) Statement of eligibility of the patent for extension under 35 U.S.C. § 156(a):

Section 156(a) provides, in relevant part, that the term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended if (1) the term of the patent has not expired before an application for extension is submitted, (2) the term of the patent has never been extended, (3) the application for extension is submitted by the owner of record of the patent or its agent and in accordance with 35 U.S.C. § 156(d), (4) the product has been subject to a regulatory review period before its commercial marketing or use, and (5) the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred.

As described below by corresponding number, each of these elements is satisfied here:

(1) The term of U.S. Patent No. 6,342,482 expires on June 22, 2019 due to the Terminal Disclaimer filed August 24, 2001 (see Exhibit D). This application has, therefore, been submitted before the expiration of the patent term.

(2) The term of this patent has never been extended.

(3) This application is submitted by the owner of record, Lilly (according to the assignment recorded in the U.S. Patent and Trademark Office on June 22, 1999, at Reel 010056, Frame 0605). This application is submitted in accordance with 35 U.S.C. § 156(d) in that it is submitted within the sixty-day period beginning on the date, January 18, 2011, the product received permission for marketing under the FFDCA and contains the information required under 35 U.S.C. § 156(d).

(4) As evidenced by the January 18, 2011 letter from the FDA (Exhibit I), the product was subjected to a regulatory review period under Section 505 of the FFDCA before its commercial marketing or use.

(5) Finally, the permission for the commercial marketing of spinosad after regulatory review under Section 505 is the first permitted commercial marketing of spinosad. This is confirmed by the absence of any new drug application approved under Section 505 for spinosad prior to January 18, 2011. For full disclosure, spinosad was previously approved for commercial marketing or use under Section 512 of the FFDCA according to New Animal Drug Applications (NADAs) No. 141-277 and No. 141-321.

(b) Statement as to length of extension claimed:

The term of U.S. Patent No. 6,342,482 should be extended by 1493 days to July 24, 2023. This extension was determined on the following basis: as set forth in 35 U.S.C. § 156(g)(1) and 37 C.F.R. § 1.775(c), the regulatory review period equals the length of time between the effective date of the initial IND on November 11, 2004 and the initial submission of the NDA on January 22, 2009, a period of 1533 days, plus the length of time between the initial submission of the NDA on January 22, 2009 to NDA approval on January 18, 2011, a period of 726 days. These two periods added together equal 2259 days.

Pursuant to 35 U.S.C. § 156(c) and 37 C.F.R. § 1.775 (d)(1)(i), the term of the patent eligible for extension shall be extended by the time equal to the regulatory review period which occurs after the date the patent was issued. The entire period under 35 U.S.C. § 156(g)(1)(B) occurred after the May 16, 2000 issue date of U.S. Patent No. 6,342,482. Thus, the 2259-day period calculated above as the term of the patent eligible for extension should not be reduced under 35 U.S.C. § 156(c) or 37 C.F.R. § 1.775(d)(1)(i).

As discussed in paragraph (11) above and as illustrated in Exhibit J, ParaPRO, a licensee to the above-captioned patent, was continuously and diligently working toward securing NDA approval for spinosad. As ParaPRO acted with due diligence during the entire period of regulatory review, the 2259-day period calculated above as the term of the patent eligible for extension should not be reduced for lack of diligence under 35 U.S.C. § 156(c)(1) or 37 C.F.R. § 1.775(d)(1)(ii).

Pursuant to 35 U.S.C. § 156(c)(2) and 37 C.F.R. § 1.775(d)(1)(iii), this 2259-day period is to be reduced by one-half of the time from the effective date of the initial IND (November 11, 2004), or the date of issue of U.S. Patent No. 6,342,482 (May 16, 2000), whichever is later, to the date of initial submission of the NDA, January 22, 2009, a period of 1533 days. One-half of this period is 766.5 days. According to MPEP § 2758, "half days will be ignored and thus will not be subtracted from the regulatory review period." Thus, the 2259-day period is reduced by 766 days, resulting in a revised regulatory period of 1493 days.

Pursuant to 35 U.S.C. § 156(c)(3) and 37 C.F.R. § 1.775(d)(2-4), if the period remaining in the term of the patent after the date of approval January 18, 2011 to June 22, 2019, a period of 3077 days, when added to the revised regulatory period (1493 days) exceeds 14 years (5113 days), the period of extension must be reduced so that the total of both such periods

does not exceed fourteen years. In this case, the total of both such periods does not exceed fourteen years and, therefore, the 1493-day revised regulatory review period is not reduced.

The period of patent term extension as calculated above is also subject to the provisions of 35 U.S.C. § 156(g)(6) and 37 C.F.R. § 1.775(d)(5). U.S. Patent No. 6,342,482 issued after the enactment of the statute, September 24, 1984 and, thus, the five-year maximum on extension as provided in 35 U.S.C. § 1.56(g)(6) and 37 C.F.R. § 1.775(d)(5) is applicable. Since this maximum is greater than the period calculated above, the term of the patent is eligible for a 1493-day extension until July 24, 2023.

(13) A statement that applicant acknowledges a duty to disclose to the Commissioner for Patents and the Secretary of Health and Human Services or the Secretary of Agriculture any information which is material to the determination of entitlement to the extension sought (*see* § 1.765):

Applicant acknowledges a duty to disclose to the Commission for Patents and the Secretary of Health and Human Services any information which is material to any determination of entitlement to the extension sought. Applicant is unaware of any such information other than that already presented in this application and attached Exhibits.

(14) The prescribed fee for receiving and acting upon the application for extension (see § 1.20(j)):

As indicated by the letter of transmittal submitted with this application, the Commissioner for Patents has been authorized to charge the filing fee of $1,120.00 and any additional fees which may be required by this or any other related paper, or credit any overpayment to Deposit Account No. 05-0840 in the name of Eli Lilly and Company and any additional fees which may be required.

(15) The name, address, and telephone number of the person to whom inquiries and correspondence relating to the application for patent term extension are to be directed: